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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,828

01/25/2006

Hidetsugu Takagaki

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EXAMINER

SIMMONS, CHRIS E

ART UNIT

PAPER NUMBER

1612

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/565,828	<b>Applicant(s)</b> TAKAGAKI ET AL.	
	<b>Examiner</b> CHRIS E. SIMMONS	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15 and 17-35 is/are pending in the application.
- 4a) Of the above claim(s) 21,23,25,27 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15,17-20,22,24,26,28 and 30-35 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/30/2008 and 08/19/2008</u> .                                | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Applicants' arguments, filed 07/30/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Objections***

In this case, claim 15 is objected to because it is currently amended but is marked as "previously presented".

According to 37 CFR 1.121, all claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended" and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include

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markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as “withdrawn — currently amended. ”

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 17-20, 22, 24, 26, 28 and 30-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 15, the term "including" renders the claim indefinite because it is unclear whether the limitation(s) following the term are part of the claimed invention.

See MPEP § 2173.05(d).

### ***Obviousness Rejection***

Claims 15, 17-20, 22, 24, 26, 28 and 30-32 were rejected under USC 103(a) as being unpatentable over Kimura et al. in view of Postma et al. **This rejection is maintained and is now applicable to newly added claim 33-35.**

Relying on Aoki et al., Applicant argues that “since the types or mode of inflammatory cells present between asthma (allergic reaction) and COPD vary, in fact,

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whether [TA-270] exhibits therapeutic effects in treating COPD, or how much therapeutic effect...[TA-270] can achieve in COPD is at least unexpected...".

Examiner does not find this argument persuasive. Applicant admits at page 7 of the response that the Aoki reference discloses that TA-270 significantly *inhibits an increase in eosinophils* among inflammatory cells. Additionally, Aoki et al. describe the tendency to inhibit the infiltration of total cells. As outlined in the prior office action, COPD is associated with an increase in the presence of inflammatory cells, such as eosinophils, in the respiratory system. Table 1 (secondary reference, S188) shows the different cells involved in the airway wall inflammation in asthma and COPD. Among the different types of inflammatory cells present in lung tissue in patients with COPD, eosinophils are present at an increased level. Accordingly, the skilled artisan would find motivation in taking advantage of the ability of TA-270 to, at least, decrease eosinophilia; additionally, the skilled artisan would also find motivation because of TA-270's tendency to inhibit the infiltration of total cells since there is also an increase in other inflammatory cell types listed in Table 1 in COPD.

At pages 8 and 9 of the response, it would appear that applicant is arguing that the compounds of the claimed invention are not based on the inhibitory effects of TA-270 on the increase of inflammatory cells as disclosed in the references. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. *See MPEP 2145 [R-6]*. In this case, Applicant asserts that the current invention is not based on its inhibitory effect disclosed in the prior art.

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Applicant believes that the improvement in FEV<sub>1</sub> discovered by applicant would make the instant invention patentable over the prior art. The examiner disagrees. Although Applicant alleges to have found that TA-270 improves FEV<sub>1</sub>, one of ordinary skill in the art would still have found reason to combine the teachings to come up with the instant invention as claimed based on the inhibitory effects of TA-270 against pulmonary inflammation.

Applicant further argues unexpected results at pages 9 (bottom) and 10. Applicant submitted a declaration (filed 07/30/2008) showing experimental data on pigs. In this experiment applicant attempted to overcome the examiners rejection by demonstrating that TA-270 does not decrease inflammatory cell infiltration. The experiment, however, would appear to support the position of the examiner, which is TA-270 would have been expected to have an inhibitory effect on inflammation to treat COPD since COPD is associated with an influx of inflammatory cells. The experiment in the declaration shows that TA-270 decreases inflammatory cells that are increased in COPD. Applicant asserts that the data shows that the commercially available compound, Theophylline, does not treat COPD in patients even though it is a known antiinflammatory compound. The examiner does not find this persuasive and refers applicant to Zhou et al. (Zhonghua Jie He He Hu Xi Za Zhi. 2006 Sep;29(9):577-82) which discloses that Theophylline does indeed improve COPD in **human patients** (see abstract). The instant claims include humans as the treated population. The instant affidavit shows test results in pigs. The affidavit's results in pigs are not representative for treatment in human patients. Therefore, the affidavit is not persuasive.

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Again, at pages 11 (bottom) and 12, applicants appears to be arguing against a commercially available compound, Theophylline. Applicant argues that Theophylline is limited to inhalable formulations only but TA-270 can also be used orally. This does not overcome the rejection. The primary reference already suggests oral administration of TA-270 at page 1321 under In Vivo Studies (second column). If applicant is arguing unfelt-need then the arguments should be clearly stated.

No claims are allowed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./



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Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612